P&G Case 7922 Serial Number 09/489,310 Office Action Dated March 17, 2004

REMARKS

Applicant thanks the Examiner for the consideration given the present application. Claims 11-15, 17-20, and 22-31 remain in the present Application.

Examiners. The first time that this case was withdrawn by an Examiner, the Applicant requested that the Appeal be reinstated because there was no basis for the Examiner's decision to withdraw the case from Appeal. The case was then assigned to the present Examiner who assured the Applicant's representative that new, "more relevant" art had been developed. And that the new reference must be dealt with before proceeding to appeal. Such is <u>not</u> the case. The references cited by the Examiner in the present rejections -when compared to the references supplied by the Applicant, and previously discussed during the prosecution of this case- are, in a word, irrelevant. Applicant views the present Office Action as an abuse of the prosecution process and respectfully requests that this case be sent to Appeal and that the fees for such Appeal be waived as they have been paid once and the Appeal withdrawn twice for no reason.

It is clear from the prosecution of this case, that Art Group 1614 will not follow the Federal Circuit's decisions in *In re Miller*, 164 USPQ 46 (CCPA 1969) and *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), preferring instead to follow the much older decision *In re Haller*, 73 USPQ 403 (CCPA 1947), which predates the patent act of 1952. As such, this case cannot be resolved by continued prosecution. The Group's attempts to deny the Applicant the right to Appeal this case are believed to be an abuse of the prosecution process.

The Rejection Under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 11 – 15, 17 – 20, and 22-31 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 3,681,091, to Kohl et al. The Applicant respectfully traverses this rejection.

The present invention is related to methods and Kits for preventing dental erosion. Both the method and Kit claims employ a beverage composition having a pH of less than about 5.0, containing a polyphosphate material. In the Kits of the present invention, the beverage is provided with instructions that it can prevent dental erosion. In the present method claims, the beverage is administered to a mammal to prevent dental erosion.

The Kohl reference is arguably directed to the use of polyphosphates for preserving foods, for example, fruit juices. The Office Action states that because the reference teaches liquids containing a polyphosphate that it invalidates the present claims. To arrive at this conclusion it is necessary for the Examiner to ignore the portions of the claims directed to the instructions of use (in the Kit claims) and the method of use (in the method claims). Applicant

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asserts that the instructions for use and the method of use are both integral and critical portions of the claims that must be given consideration under current Federal Circuit precedents. And when these limitations are considered the present claims are patentably distinguishable over Kohl and the plethora of other references cited during the prosecution of this case.

Likewise, the Examiner has rejected Claims 11 - 14, and 22-26 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 5,017,362, to Gaffer et al. The Applicant respectfully traverses this rejection.

This rejection fails for at least three reasons. As discussed above, the Office Action ignores important and patentably distinguishable portions of the claims, specifically, the instructions for use and method of use. Moreover, the Gaffer reference is related to mouthwash compositions not beverages. It is notoriously well known that mouthwashes are not intended to be consumed as a beverage. In a recent advertising campaign, one mouthwash manufacturer poked fun at how bad their own product tasted. Regardless of taste, the Examiner states that the mouthwash is intended to control the formation of calculus on teeth which is the cause of dental erosion. This is statement is unsupported be the Examiner because it is false. The Examiner need only consult one of the many oral care references cited by the Applicant to find that dental erosion is caused when acidic beverages soften the tooth enamel, allowing it to be worn away by brushing, eating or other normal oral activities. The formation of calculus plays little or no role in the attack of tooth enamel by acidic beverages. Thus, the Gaffer reference fails to anticipate the present claims for a host of reasons.

The Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 11-15, and 17-20 and 22 under 35 U.S.C. § 103(a)as allegedly being non-obvious over Gaffer et al. in view of Kohl et al. and further in view of Bahouth et al. (US Patent No. 3,894,147) or Gaffer et al. in view of Bahouth. Applicant traverses these rejections.

For the reasons discussed above, the Gaffer and Kohl references do not teach or suggest the invention of the present claims, and the Bahouth reference adds little relevant information. Not one of these three references teach or suggest the use of an acidic beverage containing a polyphosphate to prevent dental erosion. Again, to maintain the present rejection, it is necessary for the Examiner to ignore the instructions of the Kit claims and the use limitations in the method claims. Applicant admits, that at the time the present case was filed, acidic beverages containing polyphosphates were known to the art. Their use for the prevention of dental erosion was, however, not known.

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The prosecution of this case has degenerated to one legal question: does the instruction limitation in the Kit claims, and the use limitation in the method claims lend patentable weight to the present claims? The Applicant asserts that under the Federal Circuit opinions in Gulack and Miller, the instruction and use limitations of the present claims must be given consideration. And when considered in light of the prior art in this case, the claims are patentable.

Applicant further asserts that the instruction and use limitations of the present claims must be given consideration even under the Federal Circuit's more recent decision In re Ngai, ____ F3rd___ (Fed. Cir. (2004). It is true that based on the particular facts of Ngai, the Federal Circuit held that the instructions in the kit claims did not lend patentable weight to the claims. But Ngai is distinguishable on the facts. In Ngai, the instructions in the kit claim related to the use of a buffer for normalizing and amplifying an RNA population. But Ngai did not dispute that the prior art contained a kit with instructions for using a similar, if not identical buffer. No such prior art exists in this case. Interestingly, much like the present application, the Ngai application contained method claims in addition to the Kit claims. But unlike the present case, the method claims in Ngai were allowed without dispute.

Again, for all of the foregoing reasons, Applicant asserts that in view of the consistent controlling authority the claimed kits are indeed novel and non-obvious over the cited references. Applicant therefore requests that the Examiner withdraw the rejections and promptly allow the claims. If the Examiner cannot allow the present claims, then it is respectfully requested that the rejection be made final and that the case be allowed to proceed to appeal.

CONCLUSION

For all of the above reasons, it is respectfully requested that the Examiner withdraw the rejections under 35 U.S.C. §§ 102(b) and 103(a) and allow Claims 11 - 15, 17 - 20, and 22-31 as pending herein. If the Examiner believes that personal contact would be advantageous to the disposition of this case, he is respectfully requested to contact the undersigned at his earliest convenience.

Respectfully submitted,

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Dated: July 19, 2004

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